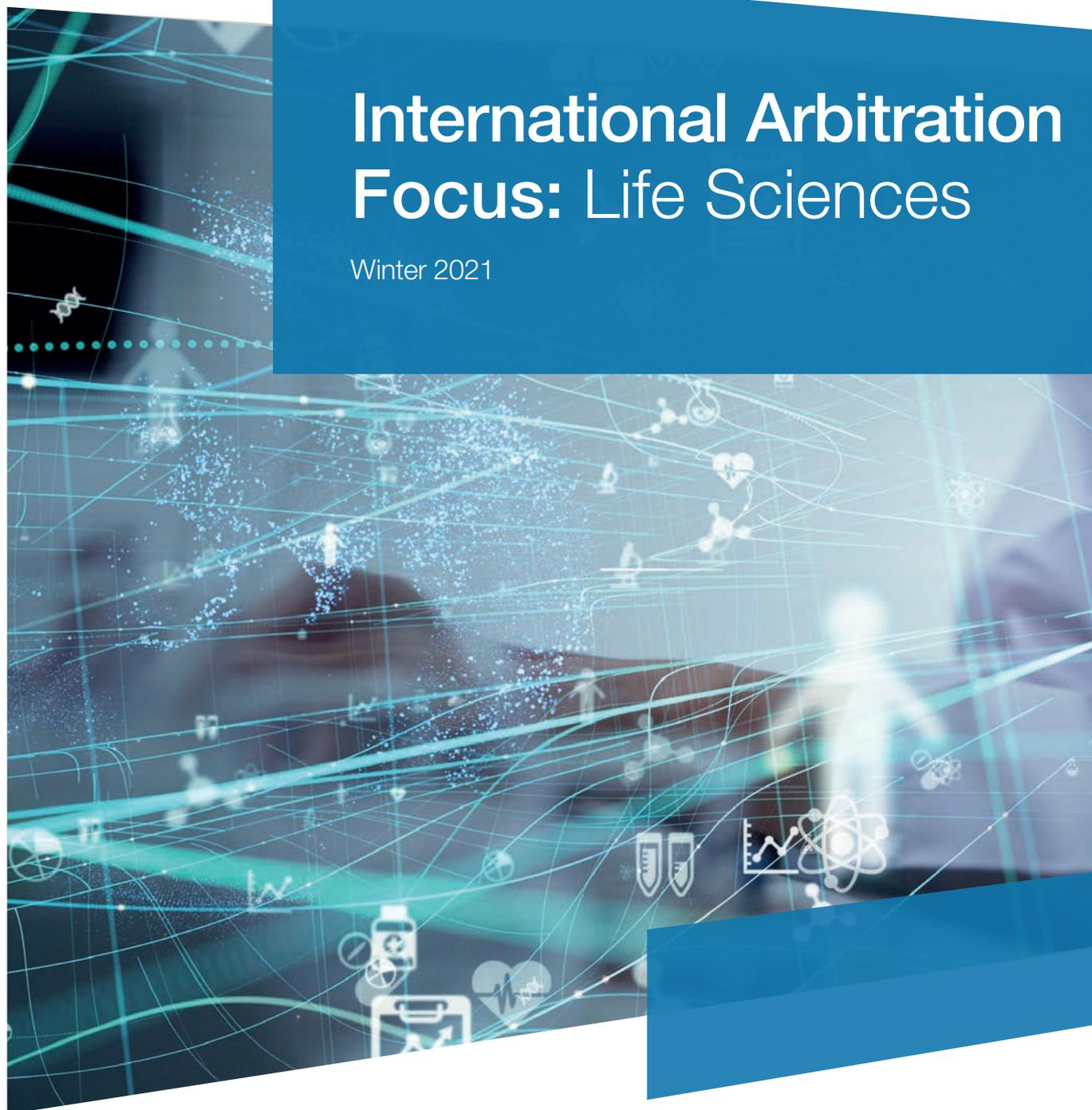


# International Arbitration Focus: Life Sciences

Winter 2021



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# Welcome

Welcome to the latest issue of Reed Smith's newsletter on international arbitration.

Reed Smith's international arbitration practice is premised on three strands: specific industries such as life sciences, certain "specialisms" (specific types of arbitrations regardless of industry, such as investment treaty arbitration), and specific geographic regions in which our lawyers are especially well-suited to advise our clients.

This issue of our newsletter focuses on the highly topical and critical life sciences sector, one of our firm's core industry focus areas. Recognized for its "stand out focus" on the life sciences industry (*The Legal 500 USA 2020*), our firm represents companies in the pharmaceutical, medical device, biotechnology, diagnostic and animal health sectors. Our international arbitration lawyers who concentrate in these fields have deep knowledge of the industry.

In this issue, lawyers from offices across our global network – including New York, Paris, London, Hong Kong, Singapore and Frankfurt – examine why arbitration is increasingly important to industry participants, and explore ways in which clients, be they large global companies, start-up enterprises, investors seeking opportunities, or trade organizations, can benefit from the protection afforded by both commercial arbitration and investment treaty arbitration.

We hope you enjoy reading this edition, and as always, we welcome your feedback.



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# Note from the Editors

Welcome to the fifth issue of *International Arbitration Focus: Life Sciences*

As the title indicates, this issue focuses on one of the most timely topics in the international arbitration arena – commercial life sciences arbitration.

While market forces have been driving a significant increase in the number of commercial life sciences arbitrations globally for over a decade, the impact that the COVID-19 pandemic has had on that growth cannot be overstated.

The pandemic has led to pharmaceutical supply chain pressures caused by global supply shortages beginning in the spring of 2020. It has given rise to issues caused by national export restrictions imposed as the pandemic took hold. It has contributed to an increased understanding of the benefits that international arbitration offers for resolving commercial life sciences disputes arising from cross-border collaborations. In short, the pandemic has resulted in a slew of new commercial life sciences arbitrations, the number of which will only increase in the future.

Our panel of international arbitration lawyers from around the globe offers a host of fascinating insights on a number of current issues that parties commonly face in those disputes, as well as commentary on cutting-edge topics.

For instance, this edition explores the numerous benefits that international arbitration offers for resolving multi-jurisdictional IP disputes, which are a vital facet of numerous commercial life sciences arbitrations.

This issue also examines the role that Hong Kong, Singapore, and India play in commercial life sciences arbitrations, as well as the manner in which those jurisdictions handle significant issues, like award enforcement and interim relief in aid of arbitration.

Authors from our global international arbitration group offer suggestions taken from the construction industry for how disputes boards could be employed in long-term life sciences collaborations to help avoid formal disputes without resorting to arbitration.

Lastly, our guest editor, J.P. Duffy, discusses the crucial role that emergency arbitration plays in resolving commercial life sciences arbitrations, particularly when parties need multi-jurisdictional interim relief that they would otherwise have to seek from multiple national courts.

Whether you handle commercial life sciences arbitrations every day or simply want to learn more about the topic, this edition of our newsletter has something for you. We hope you enjoy it, and we encourage you to reach out directly to the authors with any questions you might have.

**To access our previous newsletters, please click to view our editions on [Asia](#), [Investor-State](#), [Latin America](#) and [Construction](#).**



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# IP arbitration in the life sciences sector

## A more recent development

For businesses from the construction, shipping, and energy sectors, arbitration has long been the dispute resolution mechanism of choice. The rise in arbitration in the life sciences sector, by contrast, is a more recent development. Given the limited statistical information available, identifying the underlying causes is somewhat speculative. However, it appears fair to say that the growth in life sciences arbitration goes hand in hand with globalization.

Companies from the pharmaceutical, medical device, and biotech industries increasingly conclude cross-border commercial arrangements. It is not unusual for both parties to refuse acceptance of a dispute resolution clause that gives courts in the country of the opposite party jurisdiction. The reasons are manifold, ranging from a certain unease with differences in legal culture, or a perceived unfair advantage, to concerns about the rule of law. In such situations, dispute resolution via arbitration may be a viable option.

## Confidentiality considerations

Confidentiality is paramount in the life sciences industries. Companies from the sector invest significant amounts of money in research and development. They protect the work results through a combination of intellectual property rights and know-how. Commercial arrangements with third parties therefore often relate to the creation, use, and commercialization of intellectual property (IP), such as licenses, research and development agreements, or collaboration agreements. In addition, corporate transactions, such as M&A deals or joint ventures, are often IP driven, in the sense that the acquisition or generation of IP assets is a key business goal.

Depending on the nature of the specific project, disputes relating to such arrangements do not necessarily lend themselves to litigation. Companies from the life sciences sector and other entities engaged in research and development need to make sure that know-how relating to products or manufacturing methods remains secret, lest it lose trade secret protection. Even negotiation strategies or specific clauses in complex licenses may constitute proprietary information. For this reason, too, arbitration can be a preferred alternative to litigation and particularly litigation in courts that have extensive disclosure and public rights of access.

This observation is in line with data published by the World Intellectual Property Organization (WIPO) Arbitration and Mediation Center. According to WIPO, 15 percent of cases filed with the Center relate to life sciences, and they are often international in nature.<sup>1</sup> A significant number of cases concern patent licenses, non-disclosure, research and development agreements, and joint venture contracts.<sup>2</sup>

## Single forum and choice of law

Arbitration in the life sciences sector is not confined strictly to contractual disputes (e.g., disagreements about milestones achieved or best efforts to commercialize a new drug) and can be particularly useful in resolving multi-jurisdictional IP infringement cases.

This is because IP rights, by their very nature, are territorial. Protection is generally limited to the individual states. For example, if a German court bars a defendant from distributing a drug that infringes a German patent, this does not necessarily have implications for activities in other states where corresponding patents exist. The defendant is free to continue distribution in these other states as long as the products in question are not intended for import into Germany. Given the importance of IP rights for the life sciences sector, and owing to the principle of territoriality, companies from that sector are frequently willing to bring parallel proceedings before multiple state courts, including in the United States, Germany, France, the UK, and China, to name a few.

Multi-jurisdictional patent litigation can be costly and time-consuming, and it entails the risk of contradictory decisions. Towards the end of the global patent war of the last decade, stakeholders from the telecommunications sector increasingly opted for arbitration. This was, in part, due to the particularities of FRAND litigation (i.e., disputes about standard essential patents and fair, reasonable, and non-discriminatory licensing) and the fact that state courts were reluctant to set licensing rates for entire patent portfolios. However, it does not appear unreasonable to assume that the efforts involved in multi-jurisdictional disputes led to litigation fatigue. Arbitration, by contrast, allowed the parties to resolve complex patent infringement and licensing disputes in a single forum, under a single set of procedural rules, before a single tribunal that generally had industry expertise.



We are beginning to see similar trends in the IP-heavy life sciences sector, and particularly emergency arbitrations involving IP issues (see J.P. Duffy's article), and there have been noteworthy IP arbitrations involving companies from this industry as well. In addition to benefits arising from a single forum and the global enforceability of arbitral awards under the New York Convention, another potential advantage of arbitration lies in the parties' choice of law. When facing a case relating to a multitude of patents, parties may, for example, agree that the tribunal shall decide the (entire) dispute under a single national law, including U.S., English, German, or other laws. This avoids having to analyze the infringement question under several national laws, which may be similar, but not identical, and avoids inconsistent outcomes. In particular, the rules on patent infringement by equivalence differ significantly from jurisdiction to jurisdiction.

### Practitioner insights

With the exception of disputes about moral rights, IP disputes are in essence commercial disputes. The "checklists" that commercial and IP practitioners rely on feature similar questions, for example, about the choice of law and rules for the taking of evidence. Having said that, there are issues that require particular attention in the context of IP disputes.

For example, the drafting of the arbitration clause must be sufficiently broad. It should cover both contractual claims and claims under statutory law, so the tribunal has the power to decide the entire dispute. For instance, the use of know-how for purposes beyond the scope of a granted license may constitute a breach of contract, and it may give rise to statutory claims for the illegitimate use of third-party trade secrets. The model WIPO arbitration clause therefore refers to "any dispute (...) relating to this contract, (...) as well as non-contractual claims."<sup>3</sup>

Before embarking on an IP arbitration, it is also worth considering the likely enforcement jurisdictions and whether those jurisdictions all permit IP disputes to be arbitrated. It is generally accepted that IP infringement disputes may be submitted to arbitration, but that view is not universal, and there are substantial questions in some jurisdictions concerning the ability to arbitrate IP validity issues.

For example, the prevailing view in Germany is that an award invalidating a patent is not enforceable in that jurisdiction. Whether the patentee may be ordered to abandon a patent is moot.

Finally, yet importantly, as explained above, confidentiality is paramount for companies from the life sciences sector. The selection of the seat determines the legal framework for orders in support of the arbitration, as well as challenges of the future award. If a challenge results in a published court decision, freely accessible for anyone from the Internet, that potentially runs counter to the wishes of both parties.

A controversial 2006 decision of the Swiss Supreme Court<sup>4</sup> provides an instructive illustration. According to the underlying case, the defendant in a know-how dispute resolved under International Chamber of Commerce rules challenged the arbitral award. During the proceedings before the Swiss Supreme Court, both parties referred to the highly confidential nature of the subject matter and asked the court to refrain from publishing its decision.

The Swiss Supreme Court denied that request, however, reasoning that the public had a legitimate interest in learning about the dispute and the outcome of the challenge. Putting it somewhat bluntly, the Swiss Supreme Court stated that, if parties want to avoid any publicity, they should waive the right to challenge the arbitral award. A conceivable alternative would be to select a seat of arbitration where the courts may be more inclined to take additional measures to safeguard confidentiality.

On a more general note, therefore, parties should be conscious that confidentiality can be lost. This may happen not only at the enforcement stage but also if the award is challenged.



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# Life sciences arbitration: A Hong Kong perspective

## Introduction

This article examines reasons why Hong Kong is destined to become a preferred seat for life sciences arbitrations, not only in East Asia but also globally.

## Background

There are multiple reasons why Hong Kong is likely to become a preferred seat for life sciences arbitrations, many of which are tied to its unique relationship with Mainland China. First, Hong Kong's proximity to Mainland China, which is not only the second-largest pharmaceutical market in the world,<sup>5</sup> but home to critical industry sub-sectors, such as raw material extraction, API manufacturing, and biotech research, gives Hong Kong an inherent advantage over many other global seats.

Second, Hong Kong's judicial arrangements with Mainland China's courts, which allow for both judicial interim measures in support of arbitration and the ready enforcement of awards, make Hong Kong extremely attractive.

Third, Hong Kong has acted as a fundraising hub for Chinese biotech companies, many of which are listed on Hong Kong exchanges. According to the Hong Kong Exchanges and Clearing Limited (HKEX), Hong Kong has become the world's second-largest biotech fundraising hub since it carried out major listing reforms in 2018 that included permitting listings of pre-revenue biotech issuers and attracting biotech companies seeking international exposure, proximity to Mainland China, and deep liquid markets.<sup>6</sup> Hong Kong is home to more than 250 biotech businesses, with 100 healthcare and pre-revenue biotech listings and over 50 healthcare and biotech listing applications in the pipeline as of June 30, 2021.<sup>7</sup>

Fourth, Hong Kong acts as a research and development hub, with the Biomedical Technology Cluster of the Hong Kong Science and Technology Parks Corporation offering support for laboratory space, research facilities, and funding opportunities.

Given the increasing number of biotech companies being listed or operating (at least in part) out of Hong Kong, an increase in the number of life sciences arbitrations in Hong Kong in the future would be unsurprising. Hong Kong has long been recognized as one of the world's leading arbitration seats, being ranked the third most popular seat globally in 2021.<sup>8</sup>

In Hong Kong, there is a diverse pool of experienced arbitrators with expertise in life sciences and strong language capabilities. In addition to Hong Kong having a robust common law legal system with an independent judiciary, the Hong Kong courts are famous for their pro-arbitration stance, making it an attractive seat for many companies.

## Hong Kong's unique judicial relationship with Mainland China

The ability of Mainland China's courts to grant interim measures against Chinese companies in support of Hong Kong-seated arbitrations makes Hong Kong a particularly attractive option for pharmaceutical companies, which increasingly do business with Chinese companies at every step of the pharmaceutical supply chain. The relevant arrangement, called the Arrangement Concerning Mutual Assistance in Court-ordered Interim Measures in Aid of Arbitral Proceedings by the Courts of the Mainland and the Hong Kong Special Administrative Region (the Interim Measures Arrangement), came into force on October 1, 2019.

Under the Interim Measures Arrangement, prior to the issuance of the arbitral award, any party to arbitral proceedings seated in Hong Kong and administered by a qualified arbitral institution (such as the Hong Kong International Arbitration Centre (HKIAC)) may apply to the Intermediate People's Court of the place of residence of the party against whom the application is made or the place where the property or evidence is situated, for interim measures in accordance with Civil Procedure Law of the People's Republic of China, the Arbitration Law of the People's Republic of China, and relevant judicial interpretations.

The interim measures include property preservation, evidence preservation, and conduct preservation. As of September 7, 2021, the HKIAC has assisted in 50 such applications, 47 applications of which were made for the preservation of assets.<sup>9</sup> There were reportedly 32 decisions issued by Mainland courts, of which 30 granted the applications for the preservation of assets upon the applicant's provision of security. The total value of assets preserved by the 30 decisions amounted to RMB 10.9 billion (approximately US\$ 1.7 billion).<sup>10</sup>

Further, while there exists an Arrangement Concerning Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region which came into force in February 2000, its supplemental arrangement recently came into force on 27 November 2020 (the Supplemental Enforcement Arrangement). The Supplemental Enforcement Arrangement provides, among other things, that preservation measures may be applied for before and after the court's acceptance of an application for the enforcement of an arbitral award, thereby ensuring that preservation measures may be applied for in all phases of an arbitration.

Needless to say, in addition to Hong Kong's long-standing strengths as an arbitration hub, its arbitral arrangements with Mainland China serve as a very helpful tool that biotech or other companies dealing with counterparties based or having assets in Mainland China may take advantage of, and any such company should consider this when entering into commercial contracts and agreeing upon a dispute resolution clause. As Hong Kong is currently the only jurisdiction outside of Mainland China that has arbitral arrangements with Mainland China in relation to preservation measures, it is anticipated that Hong Kong will play an increasingly important role in the resolution of global disputes through arbitration proceedings, including life sciences and other disputes in general.



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# Connecting the dots: India, Singapore, and life sciences arbitration

India is one of the most significant global producers of life sciences products. This article examines the role that international arbitration plays in resolving life sciences disputes with Indian parties.

## Background

India has been referred to as the world's pharmacy because of the role it plays in the global life sciences market. As statistics demonstrate, that moniker is appropriate – India exports approximately 40 percent of the pharmaceutical products it manufactures, and the country provides in excess of 20 percent of the world's generic pharmaceuticals.

While India is a significant exporter of life sciences products – including IT-related life sciences products – its pharmaceutical sector, in particular, relies heavily on other countries like China to function. By some estimates, India obtains approximately 70 percent of the active pharmaceutical ingredients (API) it uses from China, and India is also highly reliant on China for the raw materials it needs to manufacture its own API.

India therefore sits in the middle of a complex international life sciences supply chain and, as the pandemic has highlighted, disputes within that supply chain are inevitable and increasing. For the reasons discussed below, international arbitration presents an attractive forum for resolving many of those disputes.

## Arbitrating life sciences disputes

In recent years, life sciences companies have increasingly adopted international arbitration to resolve cross-border disputes. The advantages of such arbitration include:

- Arbitrator expertise
- Confidentiality
- Reasonable and proportionate disclosure
- Flexible procedures
- Single venue proceedings
- A less combative environment
- [Global enforceability, particularly emergency awards](#)

Those advantages are particularly compelling for life sciences transactions that involve the Indian market, because Indian courts may not provide an acceptable venue in which to resolve many cross-border disputes. Life sciences transactions involving the Indian market increasingly contain international arbitration provisions as their default method of cross-border dispute resolution and rely heavily on Singapore in that regard.

## Shift towards institutional arbitration in Singapore by Indian parties

For a number of reasons that are beyond the scope of this article, Indian parties routinely turn to Singapore as a seat for their international arbitrations, and by default, resort to the arbitral rules of the Singapore International Arbitration Centre (SIAC) for their arbitrations. Indian parties are among the top three foreign users of the SIAC in the last decade, which has made SIAC a default choice for life sciences arbitrations involving the Indian market.

## Other global seats that are relevant to the Indian life sciences market

Of course, Singapore is not the only seat for life sciences arbitrations involving Indian parties. Many such arbitrations are seated in New York, London, Hong Kong ([see article at page 5](#) above by Donald Sham and Clara Fung), and elsewhere, depending upon the location and/or nationality of the counterparties. Moreover, many of those arbitrations are conducted under a variety of arbitral rules, including those of the International Centre for Dispute Resolution, the International Chamber of Commerce (ICC), and the London Court of International Arbitration.

As India continues to develop into a capital exporting country, parties are more frequently seating international arbitrations – including life sciences arbitrations – in India itself. This has led to international administrators opening liaison offices in India, as well as the establishment of new home-grown institutions, such as the Mumbai Centre for International Arbitration.



## The Indian Supreme Court clarifies that two Indian parties can choose a seat outside India

The second significant decision is *PASL Wind Solutions Private Limited v. GE Power Conversion India Private Limited*.

While the *PASL Wind Solutions* decision did not concern the life sciences industry, it has important implications for the industry. The Indian Supreme Court held in April 2021 that two Indian parties may choose to arbitrate at a foreign seat. It is common for Indian life sciences companies contracting with each other to choose a foreign seat (especially Singapore) in their arbitration clauses. Consequently, *PASL Wind Solutions* ratified the practice common amongst the Indian subsidiaries of international life sciences companies of seating their arbitrations outside India, even when the counterparty is also Indian.

## Pro-arbitration Indian court decisions are furthering this trend

The nascent trend in the life sciences industry towards seating arbitrations involving Indian parties in India has been assisted by the Indian judiciary, which has become notably pro-arbitration over the last decade. In fact, Indian courts have not only signaled their willingness to avoid interfering in arbitration and to enforce awards made by international tribunals but also been willing to enforce interim awards made by emergency arbitrators, as three noteworthy decisions demonstrate.

## The Indian Supreme Court signals its willingness to enforce awards against Indian parties

The first such decision is *Daiichi Sankyo Company Limited v. Malvinder Mohan Singh and others*.

*Daiichi Sankyo* was a life sciences-related arbitration that was seated in Singapore and conducted under ICC Rules. The claimant alleged that Indian brothers and prominent businessmen Malvinder and Shivinder Mohan Singh engaged in fraud when selling shares of their company, Ranbaxy Laboratories Ltd (Ranbaxy), to Daiichi Sankyo.

After receiving a US\$350 million award against them, the award debtors sought to avoid enforcement in India on public policy grounds (which has traditionally been a fruitful way to delay enforcement in India).

In 2017, the Delhi High Court enforced the US\$350 million award against the Singh brothers, and in 2018, the Supreme Court of India upheld that decision. Moreover, the Indian Supreme Court found the award debtors in contempt for failing to comply with earlier orders prohibiting them from disposing of their controlling stake in another company which would have jeopardized the satisfaction of the debt.

The *Daiichi Sankyo* decision signaled to the global life sciences industry that the Indian courts would enforce substantial arbitral awards against Indian parties, even when those parties are prominent local players.

## The Indian Supreme Court upholds the enforceability of emergency awards

The third and most recent decision that is important is *Amazon.com NV Investment Holdings LLC v. Future Retail Limited & Others*.

In *Amazon.com*, the Indian Supreme Court held – in alignment with internationally accepted practice – that emergency awards from arbitrations seated in India are recognized and enforceable under the Indian Arbitration Act.

Many life sciences arbitrations begin with emergency applications seeking interim relief. Judicial confirmation that emergency awards can be enforced, thereby giving teeth to an emergency arbitrator's interim relief, is a welcome indication of support for the arbitral process.

## Conclusion

The Indian life sciences market will continue to play an outsized role in the global life sciences sector for years to come, and the role that Singapore, and increasingly India itself, will play in resolving arbitrations in that sector will continue to develop and expand.



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# Life sciences and dispute boards: Just what the doctor ordered?

This article examines whether dispute boards could serve a role in avoiding and resolving disputes in the life sciences industry, particularly in long-term collaboration agreements.

## Background

In recent years, the life sciences industry has become defined by long-term collaborations, particularly between companies from different jurisdictions. Such collaborations can take the form of joint-development and commercialization arrangements, research ventures, co-marketing agreements, and even manufacturing relationships. They are designed to last as long as twenty years with many only realizing their full economic potential if they run the full length of their anticipated lifespan.

While arbitration can be highly advantageous for resolving formal disputes that arise under those agreements, and while joint steering committees can help settle differences before they develop into formal disputes, each process has its own limitations.

Arbitration is a formal step that parties may be reluctant to take for smaller disputes and disputes that need to be resolved but have not yet risen to the level of needing formal third-party intervention.

Joint steering committees can offer a form of informal mediation, but they are not independent of the parties. They often result in impasses that cannot be resolved without third-party intervention. Moreover, joint steering committees exist to do more than resolve differences, and they may only exist for a limited part of the collaboration in any event.

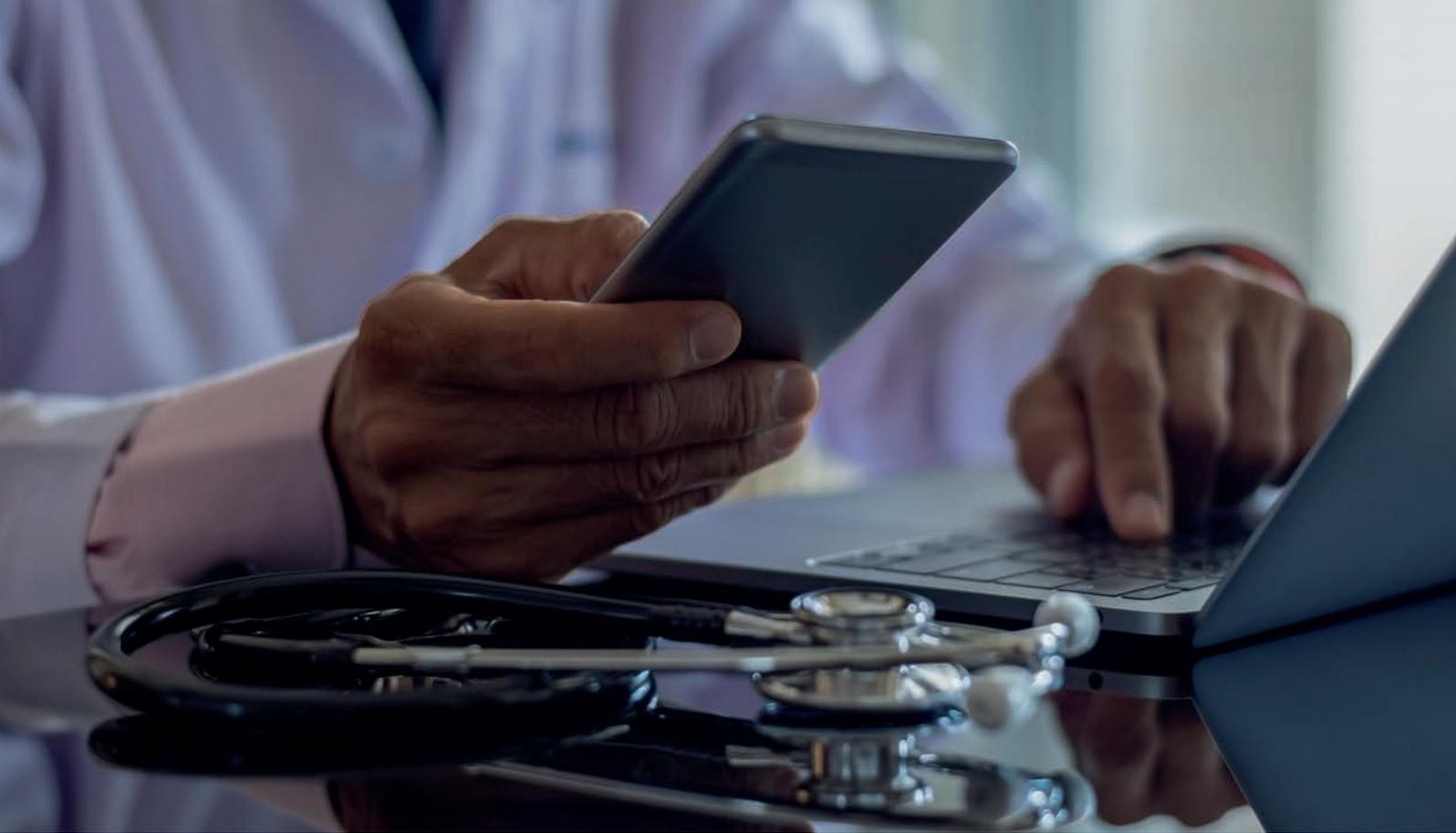
This leaves a category of disputes that falls in-between for which dispute boards – that is, bodies composed of one or three members that are independent of the parties – could be ideal. An important feature of dispute boards is that they can play a more standing, hands-on role than one-off mediation or other dispute resolution processes.

## Key characteristics of dispute boards

As noted above, dispute boards are independent bodies established by the parties that can be used to help avoid or overcome disagreements or disputes that arise during the life cycle of a contract. They are often established to resolve differences that develop during the execution of large construction contracts, and they are frequently established as independent standing bodies to which the parties can turn in order to quickly and informally resolve differences.

To those unfamiliar with the process, dispute boards may sound similar to mediation. Unlike mediation, however, standing dispute boards will be more familiar with the underlying project and transaction, and they can offer quicker resolutions with less investment and formality than mediation typically requires. This is because members of a standing dispute board will be able to gain valuable knowledge of the project throughout its life, not just when a dispute arises. This also affords standing dispute boards greater legitimacy when resolving issues, which can result in better voluntary compliance.

Dispute boards may also seem similar to the joint steering committees that many long-term collaboration agreements establish in the life sciences industry. Dispute boards, however, deal exclusively with express disagreements between the parties, whereas joint steering committees have a more positive mandate to address policy, practice, and strategic direction. Unlike joint steering committees, dispute boards are made up of independent third parties, and they therefore have a degree of neutrality that joint steering committees typically lack.



### **Differences between dispute boards and expert determinations**

While still not routine, many life sciences companies are beginning to introduce expert determination processes into their long-term collaboration agreements. This is typically being done to resolve discrete factual issues, such as safety determinations or royalty questions. This begs the obvious question as to why a dispute board would be needed.

While expert determinations may have a role to play in life sciences collaboration agreements, that role is generally limited in scope to factual issues, and it is only invoked when specific factual disputes arise. Consequently, while expert determinations might be useful in discrete situations, they play a different role to a standing dispute board.

### **Why use dispute boards in the life sciences industry?**

While the life sciences industry is unlike any other in the world, it does (at a high level) share some similarities with the construction industry. Those similarities demonstrate why dispute boards could be useful.

First, like large-scale infrastructure projects, life sciences collaborations, and particularly development and commercialization undertakings, involve multiple stages that often span many years.

Second, life sciences projects typically involve a multitude of companies that collaborate over long time frames that must all maintain good commercial relationships when disputes inevitably arise.

Third, the parties to a long-term life sciences collaboration agreement typically only realize the full economic benefit of the transaction if the agreement runs for its full duration. For instance, a twenty-year development and commercialization agreement that is terminated in the first five years is rarely profitable for either party. In contrast, that same agreement might be extremely profitable for both by year 12, and it may be much more so in its final five years (or as long as patent exclusivity exists).

Consequently, while the life sciences sector is unique, and while its undertakings seek to achieve an outcome that no other industry can claim – namely, improved human or animal health – the economic practicalities of the industry do share some similarities with other industries. Those similarities lend themselves well to dispute boards.

### **Key considerations for dispute boards**

For dispute boards to play a valuable role in the life sciences industry, they must be employed effectively, and that requires the consideration of several topics.

## Decisions can be advisory or binding

Dispute boards, like expert determinations, are ultimately creatures of contract. The parties are free to decide whether the results should be advisory or binding. They are also free to select the governing procedural rules in that regard, which offer a panoply of finality options. For instance, the International Chamber of Commerce Rules provide for three types of dispute boards: a Dispute Review Board, which issues non-binding recommendations, a Dispute Adjudication Board, which issues binding decisions, and a Combined Dispute Board, which issues both.

In the construction industry, dispute board clauses typically provide that decisions are preliminarily binding but can be reviewed or revised through a final mode of dispute resolution, such as arbitration. They also provide a period within which a party that wishes to contest the dispute board's decision must issue a notice of dissatisfaction, failing which the decision will be deemed final and binding. The objective of such provisions is to solve disputes as they arise during the project, with minimum impact. The parties have to comply with the dispute board's decision, allowing the project to continue but may reserve their right to contest the decision later through arbitration.

In the life sciences industry, this approach could be highly advantageous. First, parties would likely only be turning to a dispute board for assistance when a joint steering committee cannot provide it, or when no joint steering committee exists. In those circumstances, a binding decision could be very helpful.

Second, a binding decision will either move the collaboration ahead by keeping the project going or result in an arbitration to resolve the dispute. Either way, there will be finality, which is highly advantageous in a long-term collaboration.

## Are dispute board decisions enforceable?

While significant questions exist about the enforceability of dispute board decisions, that issue can be easily resolved by contractually providing that a party can immediately commence an arbitration to enforce a dispute board decision. That not only provides a legal enforcement solution but also provides a practical enforcement incentive as well because in the vast majority of cases, arbitral tribunals will consider well-reasoned dispute board outcomes to be highly persuasive.

## Confidentiality

One feature of the life sciences sector that makes it uniquely different from other industries is the high level of confidentiality needed to protect the IP, trade secrets, and know-how that generally emanate from any long-term collaboration. This applies particularly to development and commercialization collaborations, which may start with a molecule, but end with the distribution of an approved pharmaceutical product many years later. The participants in those arrangements generally require any third parties involved to accept very stringent confidentiality obligations, and the participants might be reluctant to give dispute board members access to the most intimate details of their projects.

This concern, which is highly valid, can be addressed in two simple ways. First, the members of the dispute board can be made subject to the same strict confidentiality requirements that any third party, such as a manufacturer, typically accepts.

Second, dispute boards can be established as standing bodies, which not only ensures its members have a detailed understanding of the project at the time differences arise but also minimizes the number of third parties to whom sensitive information is disseminated.

## Conclusion

Dispute boards have proven to be very effective in the construction industry and could play an equally valuable role in long-term life sciences collaboration agreements.



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# Investment treaty arbitration in the life sciences sector

While investment treaty arbitration has not historically been a popular method of dispute resolution for life sciences companies, recent trends indicate that is changing. This article examines the reasons why.

## Background

Investment treaty arbitration is a process that allows foreign investors to assert claims directly against host states for state action for breaches of international investment agreements. Foreign states consent to allow such claims to be brought against them by executing bilateral or multilateral investment treaties that are presumed to encourage foreign investment in the host state by affording investors a panoply of legal protections, such as the right to fair and equitable treatment and the right not to have investments expropriated without fair and adequate compensation.

To assert an investment treaty claim against a host state, the investor must show that some negative action was taken against the investment or investor either directly by the state or that can be attributed to the state. Those negative actions can be as straightforward as the host state seizing a manufacturing facility owned by the investor or as nuanced as the host state passing legislation that impairs the investor's intellectual property rights in the host state.

## Investment treaty arbitration in the life sciences sector

As the life sciences sector becomes increasingly global, the potential for investment treaty claims by life sciences companies is concomitantly escalating. That is unsurprising because the life sciences sector is one of the most heavily regulated in the world, which creates numerous opportunities for states to take actions that can give rise to claims. For instance, states:

- Control access to their markets by requiring regulatory approval for life sciences products to be distributed in their countries
- Continually control the manner in which products can be marketed and advertised
- Implement large-scale product tenders that may then be distributed through government-owned medical facilities
- Provide (or fail to provide) intellectual property protection to life sciences companies doing business within their borders
- Legislate the manner in which consumers can seek redress against life sciences companies for things like alleged safety issues
- Adjudicate those and other claims through their court systems

Every one of those touchpoints could result in actions that are alleged to violate an investment treaty and, as statistics indicate, life sciences companies are becoming more attuned to that fact. Specifically, between 2000 and 2020, 14 investment treaty arbitrations involving life sciences companies have been reported. Those claims have been brought by major U.S., Canadian, and French companies, as well as by private individuals from the United States and the UK, against a number of different states including the United States and Canada, Ecuador (including a claim brought by Pfizer, which was subsequently withdrawn), Poland, and Kazakhstan.



Claims against Saudi Arabia and Venezuela remain pending and, with export restrictions arising from COVID-19 being imposed, as well as discussions about compulsory licensing of vaccines and other products, the potential for future claims appears real. Consequently, all indications suggest that the number of investment treaty arbitration claims will continue to rise in the future.

## The requirements for obtaining treaty protection

To assert investment treaty claims, life sciences companies must ensure they satisfy a number of requirements.

First and foremost, life sciences companies must have structured their foreign investments in a way that affords them investment treaty protection. This process, known as investment treaty structuring, is akin to the process companies frequently engage in when seeking tax treaty protection, and with approximately 3,000 bilateral investment treaties in force globally and a number of multilateral investment treaties in force as well, routing an investment through a jurisdiction that affords investment treaty protection is oftentimes challenging. It is also critical because nothing is more deflating than seeing a host state take steps that would be actionable but that cannot be meaningfully addressed because the investment was not properly structured.

Second, and relatedly, life sciences companies must ensure that they comply with nationality requirements under the relevant investment treaty, which generally requires the investor to be a national of a state party to the treaty other than the host state. In other words, a life sciences investor must be either incorporated in a state that is a party to the treaty or a private individual who is a national of that other state, such as a foreign shareholder, but cannot typically be deemed to be a citizen of the state against whom the claim is being asserted.

Third, life sciences companies must have made an investment in the host state that satisfies the investment definition set forth in the relevant investment treaty, and such definitions are generally very broad. For instance, investments have been defined as “every kind of asset” or “every form of investment,” including shares or other forms of participation in local companies, tangible and intangible property, licenses, concessions, and any rights given by law or contract or by a decision of a public authority. Notably, this includes not only regulatory licenses to do things like sell life sciences products but also intellectual property rights in those products.

Ultimately, whether an investment in the life sciences sector will be entitled to treaty protection will depend on the treaty wording, as well as the nature of the investment itself. Some investment treaties define investments to include:

- “[R]ights with respect to copyrights, patents...” or “patentable inventions,” which obviously include the IP rights that oftentimes attach to life sciences products.
- “[R]ights given by the decision of a public authority, which could include a regulatory approval to sell a product in the host country.
- “[A]ny asset having an economic value,” which could also include drug approvals, as well as things like import permits.
- “[C]laims to money,” which could arise from voluntary licenses for the use of patents and trademarks, compulsory licenses, and contracts between pharmaceutical companies and state companies or agencies for developing or selling drugs.
- “[I]ntangible property” that is capable of being “owned” and assigned to third parties, such as an application to register a trademark (*Anheuser-Busch v. Portugal*), or a registered trademark and a license to use a trademark (*Bridgestone v. Panama*).

As that list demonstrates, the possibilities are relatively broad, and tribunals have even determined that drug development and production rights and drug patents themselves constitute an “investment” entitled to protection.

The possibilities are not endless, however, and tribunals have declined jurisdiction over life sciences claims on grounds that no investment entitled to protection was made. For instance, in a claim brought by Apotex against the United States, the tribunal held that expenses incurred in (1) seeking Food and Drug Administration (FDA) approval, (2) the purchase of materials and ingredients in the United States for the intended manufacture of products abroad, and (3) conducting litigation and establishing an agent in the United States for the purpose of corresponding with and making submissions to the FDA, were all insufficient to qualify as an “investment” under NAFTA.

## The rise of intellectual property claims in life sciences investment treaty arbitrations

While the life sciences sector sees its fair share of universal standard claims, such as a claim by Merck that the Ecuadorian courts denied it justice, claims over the repudiation of a long-term sales contracts (*Qatar Pharma v. Saudi Arabia*), and claims for the seizure of manufacturing facilities (*Santamarta v. Venezuela*), many claims in the life sciences sector concern interference with intellectual property rights and other regulatory matters.

For example, in *Servier v. Poland*, frustration of the investor's legitimate expectations was successfully claimed in relation to the cancellation of marketing authorizations, leading to an expropriation of Servier's investment and discrimination against the French pharmaceutical company in favor of local competitors. Similarly, in *Eli Lilly v. Canada*, Eli Lilly's successful NAFTA claim against Canada related to the sudden adoption by Canadian courts of a stricter approach to patent invalidation in relation to what was promised to the patent holder. Two claims by Canadian pharmaceuticals company Apotex against the United States (dismissed for lack of jurisdiction) were driven by Apotex's efforts to accelerate entry into the U.S. market.

As debates about compulsory licensing of vaccines and about access to other products during the pandemic continue, it seems likely that the number of IP claims will rise in the future.

### Conclusion

When considering an investment in a foreign jurisdiction, it is important to consider the availability of investor protections and to structure the investment so as to take advantage of applicable treaties and domestic investment laws. It is also important to ensure that the contractual framework is such that it supports and facilitates investor protections, particularly in politically unstable and/or developing countries where there is a high risk of governmental or regulatory interference, or when investing in high-profile assets. Life sciences/pharmaceutical companies would be well advised to consider the crucial and valuable protections afforded by investment treaties in addition to contractual rights at an early stage in project planning, ideally before establishing project entities or making investments.



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# The value of emergency arbitration in life sciences disputes

Emergency arbitration has become a common feature in life sciences arbitrations over the last five years, and particularly during the COVID-19 pandemic. This article examines the factors that have made emergency arbitration an attractive alternative to judicial interim relief in commercial life sciences arbitrations.

## Discussion

To understand why emergency arbitration has become so common in life sciences arbitrations, it is first necessary to understand what emergency arbitration is, and why it is employed in commercial life sciences disputes.

### A. What is emergency arbitration?

Emergency arbitration is a procedure that allows parties to get quick interim or conservatory relief – often in two weeks or less – from a sole emergency arbitrator, instead of from a national court, in the time before a full merits tribunal is appointed. Emergency arbitration fills the gap that exists between the time arbitration is commenced and the time that a full merits tribunal is constituted for those parties that need interim or conservatory relief at the outset of a formal dispute and who do not wish to approach a national court or courts for that relief.

### B. Why is emergency arbitration employed in commercial life sciences disputes?

While section E below examines the benefits that emergency arbitration offers over judicial interim relief in detail, emergency arbitration has become a frequently employed tool in commercial life sciences arbitrations for two reasons. First, many life sciences disputes require time-critical issues to be resolved at the outset of the formal dispute – be it judicially or in arbitration – such as intellectual property (IP) and trade secrets issues, or issues regarding the continued performance of ongoing contractual obligations. Second, many of those issues are multi-jurisdictional in nature and require relief in multiple locations at the same time. Emergency arbitration is an ideal tool for addressing both of those needs.

### C. The history of emergency arbitration

While emergency arbitration has become a common occurrence in life sciences arbitrations over the last five years, it is a relatively recent addition to the international arbitration landscape.

In the 1980s, questions arose as to whether merits arbitrators could grant interim relief as part of their inherent powers. To definitively resolve those questions, institutions began revising their rules to expressly give arbitrators the power to grant that relief.

During the course of those amendments, questions arose about how parties might obtain relief in arbitration or outside of court in the period of time before any merits arbitrators were appointed. Those questions led to the emergency arbitration concept entering the arbitration landscape in the 1990s.

The International Chamber of Commerce (ICC) was the first major institution to introduce emergency arbitrator processes in 1990 when it promulgated its Rules for Pre-Arbitral Referee Procedure. The Pre-Arbitral Referee Procedure, which still exists today, is a set of opt-in rules that permit the ICC to appoint a referee that can grant relief before a merits tribunal is constituted. While the Pre-Arbitral Referee Procedure was a significant innovation in 1990, it has only been employed by parties 17 times since its inception.

In 1996, in recognition of the fact that many IP disputes require immediate interim relief before a full merits tribunal can be appointed, the World Intellectual Property Organization (WIPO) proposed adopting opt-in emergency arbitration rules. Ultimately, however, WIPO declined to implement the rules.

In 1999, the American Arbitration Association (AAA) introduced its Optional Rules for Emergency Measures of Protection as part of its Commercial Arbitration Rules.



As the name indicates, those rules were also optional and required affirmative assent from the parties. They did, however, receive positive feedback, and helped pave the way for steps that the International Centre for Dispute Resolution (ICDR), which is the international arm of the AAA, took a few years later.

In 2006, emergency arbitration as it is understood today took a critical leap forward when the ICDR introduced the first default, opt-out emergency rules as part of its 2006 rule revisions. Under the 2006 ICDR Rules, emergency arbitration became a default process, instead of an opt-in procedure, that the parties accepted by agreeing to arbitrate under those rules.

The introduction of the 2006 ICDR emergency rules resulted in two crucial outcomes. First, by making the emergency rules a default process, rather than an elective option, many more parties began to use emergency arbitration. Second, as more parties employed emergency arbitration and gained experience with it, its benefits became much clearer, and the process gained widespread acceptance in the international arbitration community.

The introduction of the ICDR default emergency arbitration rules was so successful, in fact, that over the next ten years, almost every major arbitral administrator adopted default or opt-out emergency arbitration rules, as the following chart demonstrates.

Year of adoption	Administrative institution
2010	Singapore International Arbitration Centre and Stockholm Chamber of Commerce
2012	ICC and Swiss Chambers
2013	Hong Kong International Arbitration Centre
2014	London Court of International Arbitration and International Institute for Conflict Prevention and Resolution
2015	China International Economic and Trade Arbitration Commission

Consequently, over a nine-year period from 2006 to 2015, nine of the largest and most-influential arbitral administrators in the world implemented default emergency arbitration procedures, which made the process a globally accessible one.

#### D. Emergency arbitration’s key features

While emergency arbitration procedures vary slightly under each institution’s rules, there are several features that are common to every emergency arbitration conducted under all of those rules. Those features include:

**Short deadlines** – emergency arbitration is designed to provide fast outcomes and results, so most institutions appoint emergency arbitrators within 24 to 48 hours of the emergency request being filed (and the filing fee being paid), and generally require those arbitrators to issue emergency awards or orders within two weeks of the application being registered. Those short deadlines and quick timelines mean that emergency arbitrators will impose aggressive written submission schedules upon the parties, and will generally focus any oral hearings they might hold (and there is no general requirement that they hold any) on legal arguments, rather than witness cross-examination.

**Single emergency arbitrator** – regardless of the number of arbitrators the arbitration clause calls for or the method of their appointment, emergency arbitrations are conducted by a single emergency arbitrator that is appointed by the arbitral institution, to which parties consent by selecting the arbitral rules in question.

**Limited or no disclosure** – the short and strict deadlines for issuing emergency awards generally preclude anything but the most cursory document disclosure from the opposing party, so parties bringing emergency applications must generally possess the evidence they need to support their emergency application at the time they lodge it and should not expect to receive much more after doing so.

**Non-binding results** – emergency arbitral awards do not bind the merits arbitrators, who can accept, modify, or vacate emergency awards, which means that emergency awards and orders are inherently interim in nature.

**No ex parte relief** – with the exception of the Swiss Rules of International Arbitration, all major institutional rules require emergency applications to be on notice, as *ex parte* relief is generally considered impermissible under Article V of the New York Convention.

**Results do not bind third parties** – arbitration is a consensual form of dispute resolution that only binds the parties to the arbitration agreement, so emergency arbitration awards cannot legally bind third parties, like banks, customers, or other third parties that hold counterparty assets.

Consequently, emergency arbitration is a quick process that allows for urgent relief in the frequently long period before a full merits tribunal is appointed. Given that emergency awards are non-binding, do not permit for *ex parte* relief, and cannot legally bind third parties, one may wonder why parties would ever choose emergency arbitration over interim judicial relief from a national court. As the following section explains, emergency arbitration offers significant advantages over interim judicial relief in many circumstances – particularly in life sciences disputes – despite its inherent limitations.

### **E. The benefits that emergency arbitration offers over interim judicial relief in life sciences disputes**

Emergency arbitration offers several advantages over interim judicial relief in life sciences disputes, each of which is discussed below.

#### **1. Single forum relief and one-stop shopping**

As section B above notes, life sciences companies frequently require multi-jurisdictional relief at the outset of a formal dispute. For instance, a pharmaceutical licensor may need to terminate a worldwide license and may need to secure its IP and stop the licensee from continuing to distribute a product. The licensor has two options in those circumstances.





First, it can engage multiple sets of counsel to approach multiple national courts in each jurisdiction in which it needs relief (for example, courts in the United States, Europe, Asia, and Latin America), and if it does so, each national court it approaches will:

- Assign a judge to the case that may not have any life sciences expertise.
- Follow its own individual court procedural rules.
- Apply its own national laws.
- Move at its own pace, particularly during events like COVID-19, but also during routine holiday periods and other times of local significance.
- Reach its own outcome when deciding whether to grant whatever relief is available under its national laws, which may be entirely different from the relief available under other relevant national laws.

Notably, the outcome that each of those national courts reaches can be wholly inconsistent with the outcome reached by other national courts, will be limited in geographical reach to the jurisdiction of the court that issued the outcome, and will generally not be readily enforceable in other jurisdictions around the globe.

Alternatively, that same licensor can engage one set of counsel to approach one emergency arbitrator, who is likely to have life sciences expertise, and who will apply one set of procedural rules and one governing law (generally) that the licensor has itself designated in the license, which can result in one emergency award that grants consistent relief that may not be available in many of the national courts the licensor would otherwise have had to approach.

Critically, that emergency award can be readily and concurrently enforced in multiple jurisdictions around the globe under the New York Convention, regardless of whether the enforcement court could have granted the same relief on the merits that the emergency award does. The choice in those circumstances for life sciences companies is usually an easy one – emergency arbitration.

## 2. Emergency arbitrator expertise

Institutions typically appoint experienced emergency arbitrators who are knowledgeable about the industry and substantive area of law they will be asked to address. In contrast, national courts will generally appoint whatever judge is available (or one randomly selected), who may or may not have any industry expertise at all. When quick relief is needed, life sciences companies do not want to spend their time educating the adjudicator about the industry as opposed to the dispute itself, so emergency arbitration offers a preferable alternative to judicial interim relief.

## 3. Confidentiality

Emergency arbitration is a confidential process that allows applicants to seek interim relief without disseminating sensitive commercial information to the world (unless enforcement in a court with public rights of access becomes necessary).

For instance, if a party to a joint development agreement believes that its collaboration partner is abusing its trade secrets, that party can commence an emergency arbitration with little fear that bringing the action will further expose the very trade secrets that spawned the dispute in the first place.

## 4. Speed

Emergency arbitration provides an excellent alternative to those courts around the world that cannot grant quick interim relief, or that cannot grant interim relief in the two-week timeframe that most institutional rules envision, particularly during challenging time periods like the COVID-19 pandemic.

For example, a medical device manufacturer might need an order directing its foreign distributor to stop selling competitive products in a jurisdiction in which the courts are either closed or severely backlogged because of COVID-19, or in which the courts generally move slowly as a matter of course. In those circumstances, emergency arbitration offers an ideal alternative because it is quick and efficacious.

## 5. A panoply of available remedies

Emergency arbitration allows applicants to obtain interim remedies that may not be available in every jurisdiction in which they might need relief – such as a worldwide freezing order or an injunction when money damages might still compensate the applicant – but which can nevertheless be enforced in those jurisdictions as a New York Convention award.

For instance, a biotech company might need a collaboration partner to physically transmit research products it is obligated to send that might be critical to ongoing development efforts, but that might not be “unique” in the way many common law courts require to grant specific performance. In those instances, an emergency arbitrator can order relief that a court might be unable or unwilling to grant and can have that same court enforce the award.

## 6. Global enforceability

One of the primary advantages that emergency arbitration offers over interim judicial relief is the realistic possibility for simultaneous global enforcement. Simply stated, the New York Convention has 170 signatories in which an emergency award can be enforced, and there is simply no equivalent treaty for judgments that allows for anything approaching that reach, and particularly not interim judgments.

A simple example demonstrates the point. If a party to a co-development agreement needs an injunction to stop a collaboration partner from infringing on its IP rights, that party can start suing around the world and hope for the best, or it can bring one quick emergency arbitration and seek to enforce the emergency award simultaneously in every New York Convention jurisdiction in which it needs relief.

While some jurisdictions might refuse to enforce the emergency award under the New York Convention on grounds that the emergency award is interim in nature, most will enforce it. Moreover, in any jurisdiction that does not enforce emergency awards, the prevailing party should have a much easier time obtaining interim judicial relief when it can present a favorable emergency award that was issued by a reputable arbitrator.

Accordingly, while emergency arbitration is not ideal for every situation, and particularly not when *ex parte* relief or relief against third parties will be needed, it frequently offers significant advantages over judicial interim measures in appropriate circumstances. As the following section explains, those circumstances include instances where the relevant jurisdictions will enforce an emergency award, because not every jurisdiction will do so because of the interim nature of the award.



## F. Emergency arbitration's limitations

Emergency arbitration is not the ideal solution to every problem, and it has inherent limitations that render it inappropriate in some circumstances.

First, arbitration is a creature of contract, so it can only bind parties that have agreed to it, which means that emergency awards can only bind the parties to the arbitration. Consequently, emergency awards cannot bind third parties like a contract research organization (CRO), supplier, or financial institution, so if a life sciences company needs relief that implicates third parties, judicial relief will be necessary. For instance, if a pharmaceutical company in a dispute with a collaboration partner needs to attach Active Pharmaceutical Ingredients (API) held by a manufacturer or research held by a CRO, an emergency award may not be helpful. That said, the pharmaceutical company might nevertheless achieve the same result that a third-party attachment would by seeking an emergency award enjoining the collaboration partner from disposing of the API or destroying the research.

Second, with the exception of the Swiss Rules, parties cannot obtain *ex parte* emergency awards, so if *ex parte* relief is truly needed, court remains the only real option. For instance, if a life sciences company needs *ex parte* relief to prevent a collaboration partner from imminently stealing trade secrets and does not want to tip the partner off, judicial relief will be necessary.

Third, there are still jurisdictions that will refuse to enforce emergency awards on grounds that those awards are not final within the meaning of Article V of the New York Convention. If a life sciences company needs emergency relief in a jurisdiction that does not currently enforce emergency awards, and it believes the counterparty will not voluntarily comply with the emergency award (and there are many built-in enforcement incentives that frequently result in voluntary compliance), judicial relief remains preferable. That said, there is a clear global trend towards enforcing emergency awards and, as the article by Timothy Cooke and Khyati Raniwala demonstrates, jurisdictions like India are moving into the enforcement camp.

Accordingly, while the three limitations set forth above can be significant, they do not impose barriers in many cases. Consequently, while life sciences companies need to consider those limitations when formulating their interim relief strategies, they can oftentimes quickly move beyond them.

## Conclusion

Emergency arbitration is a valuable tool that has become increasingly common in cross-border life sciences disputes during the COVID-19 pandemic. The advantages emergency arbitration offers ensure that it will continue to be a common feature in life sciences arbitrations well after the pandemic is over.



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